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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/609,301	06/30/2000	Donald L. Morton	JWCI:031US	2510

7590 09/11/2003

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600 Congress Avenue Suite 2400  
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EXAMINER
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SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/11/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/609,301

Applicant(s)

MORTON, DONALD L.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other:  |

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#### DETAILED ACTION

Claims 1-57 are pending and are considered on the merits.

#### Claim Rejections - 35 USC § 112 INDEFINITE

Claims 1-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite about 0.1% to 6% carbon particles. However, % used alone is always indefinite. Is this a percentage by weight or volume of what weight or volume?

Claims 11-16 recite the diameter of the carbon particles. However, it is unclear if this measurement is the diameter of the carbon particles before or after suspension. According to Hagiwara *et al.* [U], carbon particles of 21 nm diameter are used to produce a suspension having a particle diameter of 150nm (CH 40), thus it is unclear to what the diameter refers. Further, is this a mean diameter or an absolute diameter? Please point to the location in the specification for support in the response.

Claim 55 appears to have an improper subject-verb relationship.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

Claims 1-25, 30-35, 37-46, 48-54 and 56 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Lucci *et al.* [C25].

The claims are directed to a method of using carbon particles 0.1 to 6% to identify lymph nodes and diagnose/stage/predict neoplastic tissue in the lymph node.

The references are relied upon as explained below.

Lucci *et al.*, published July 1999, teaches a method of identifying lymph nodes by injecting carbon dye and isosulfan blue to aid in sentinel node identification in melanoma and breast cancer. The carbon particles are from 0.1 to 6 microns in diameter (p. 51, last paragraph).

Claims 1-16, 22, 23, 40, 41, 44, 45, 47-55 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kitamura *et al.* [C20].

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Kitamura *et al.* [C20] disclose a method of visualizing lymph nodes for gastrectomy comprising administering CH-40 with a particle size of 20 nm and a concentration of 0.7% according to the referenced article of Hagiwara *et al.* [C15].

Although the numerical range for the carbon particles in the claimed method is less than 20 microns, use of the term "about" as a modifier of the numerical range may be interpreted to be up to 20 microns. Cancellation of "about" and incorporation of the diameter of the carbon particles along with clarification of the above 112, 2<sup>nd</sup> rejection related to diameters will remove this reference.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lucci *et al.* [C25].

The claims have been discussed above.

To the extent that the reference of Lucci *et al.* does not disclose whether the carbon dye purchased from Sanford Corporation is a furnace black, thermal black or furnace black, acid, neutral or basic, all of these types of carbon black are assumed to be equivalents, that is non-critical types of carbon dye, in the absence of evidence to the contrary.

The use of the various dyes mentioned in claims 26-30 are assumed to be equivalents of isosulfan blue in the absence of evidence of criticality.

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitamura *et al.* [C20].

The claims are drawn to the use of a furnace black, thermal black or furnace black, acid, neutral or basic; all of these types of carbon black are assumed to be equivalents, that is non-critical types of carbon dye, in the absence of evidence to the contrary.

Claims 1-22 rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,205,352 [A] and Kitamura *et al.* [C20].

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The claims have been discussed above.

US 6,205,352 disclose a method of identifying sentinel nodes by administration of marking agents. The marking agents is preferably about 10-200 microns in diameter. A marking agent might be colloidal carbon particles or lymphazurin blue (col. 4, l. 41-45).

The primary reference does not disclose the concentration of colloidal carbon particles used as a marking agent.

Kitamura *et al.* disclose the use of colloidal carbon particles in a concentration of 0.7% according to the referenced method of Hagiwara *et al.* [C15].

The use of a concentration of carbon particles of about 0.7% in the method of US 6,205,352 would have been obvious when taken with Kitamura *et al.* who teach the use of this concentration to identify nodes.

Claims 23-32, 34, 35, 39-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,205,352 [A] and Kitamura *et al.* [C20] as applied to claims 1-22 above, and further in view of US 5,732,704 [B].

US 5,732,704 disclose the use of a group of dyes termed, "vital blue dye" to visually identify a sentinel node (col. 3, l. 24).

The concomitant use of carbon particles and a blue dye would have been obvious because both have been used in the prior art to identify sentinel nodes.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

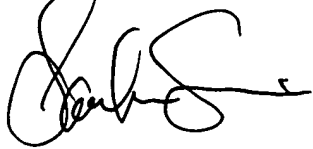
Removal of the reference by Kitamura *et al.*, that is, distinguishing the instantly used carbon particles from CH40 preparation coupled with clarification of the meaning to the diameter of the instant carbon particle would advance prosecution significantly.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions and/or additions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
September 9, 2003